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### **REMARKS**

#### **Status of the Claims**

The claims in this application are claims 1, 3-8, 10-12, 15-41, 43, 44 and 46-69. Claims 39-41, 43, 44 and 46-68 have been withdrawn from consideration pursuant to a restriction requirement.

#### **Rejection under 35 USC § 112, first paragraph**

Claims 1, 3-8, 10-12 and 15-38 have been rejected under 35 U.S.C. 112 as lacking description in the specification as filed. This rejection and its accompanying remarks are respectfully traversed.

This appears to be the type of rejection based on alleged new matter. The first amendment to claim 1 is supported in *haec verbis* in original claim 9 and does not appear to be the basis of this rejection.

The second recitation added to claim 1 by amendment reads "wherein visibility of detectable species associated with said hydrogel polymer to magnetic resonance imaging is modified by varying the degree of said cross-linking." This recitation finds support in the specification as filed. At paragraph [0033] the following is disclosed.

[B]y varying the degree of cross-linking, the magnetic environment experienced by detectable species . . . may be modified relative to the magnetic environment surrounding the medical device, thereby resulting in enhanced visibility under MRI . . . .

This quotation is in terms that are equivalent, rather than identical, to the language added by the amendment. Identical phrasing, however, is not the test for new matter or description or lack thereof. *In re Wertheim* 541 F.2d 257, 265, 191 U.S.P.Q. 90, 98 (CCPA 1976). It is only necessary to recognize that applicant invented what is claimed. *In re Wilder*, 736 F.2d 1516, 1520, 222 U.S.P.Q. 369, 372 (Fed. Cir. 1984), *In re Herschler*, 591 F.2d 693, 200 U.S.P.Q. 711, 717 (CCPA). If required, the claim recitation, which is equivalent to the above quoted paragraph of the specification, can be added by amendment to the descriptive portion of the specification. *In re Benno*, 768 F.2d 1340, 226 U.S.P.Q. 683 (Fed. Cir. 1985).

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Additional support can be found in paragraph [0087]. There in Example 6, the "effect of varying degree of cross-linking on the relaxation time of protons associated with the hydrogel polymer was determined." Three different degrees of cross-linking were tested, and the conclusion was that "a hydrogel polymer can be adapted by cross-linking to various degrees to [the] modify relaxation time," thereby modifying MRI visibility. The word "the" is an obvious typographical error. Thus, Example 6 also demonstrates conclusively that applicants were in possession of the claimed subject matter when the application was filed.

Reconsideration and withdrawal of the rejection under 35 U.S.C. 112 are therefore requested.

**New matter vis-à-vis prior art**

In the rejections over the prior art, a discussion of which follows, it appears possible that the examiner may not have considered the claims as amended, because of the purported new matter. If so, the treatment of the claims was erroneous. See MPEP 706.03(o), Examiner Note 3.

In the following remarks, the abbreviated citations used in applicants' first response will be used.

**Rejection under 35 U.S.C. 102(b) over DiCosmo**

Claims 1, 3-5, 30 and 35 have been rejected under 35 U.S.C. 102(b) as being anticipated by DiCosmo. This rejection and its accompanying remarks are respectfully traversed.

The DiCosmo device is used to deliver drugs from a hydrogel. DiCosmo does not even mention magnetic resonance imaging, much less the concept of cross-linking a hydrogel polymer to a degree sufficient to render a medical device visible under MRI. See *Ex parte Rubin*, 5 U.S.P.Q.2d 1461(BPAI 1987).

For a reference to anticipate a claim it must disclose each and every element of the claim. See MPEP 2131 and cases cited therein, especially *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989) and *In re Marshall*, 578 F.2d 301, 304, 198 U.S.P.Q. 344, 346 (CCPA 1978).

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Although instant claim 1 is drawn to a product, it defines the product at least partially as a product- by-process: "adapted by cross-linking" and "modified by varying." These process features are clearly lacking from DiCosmo, and the reference thus fails as an anticipation.

The examiner relies on an asserted inherency of the claimed invention in the product of the reference. Even apart from the distinction pointed out directly above, there is absolutely no reason to believe the properties of the devices here claimed would be inherent in the reference. Furthermore, reliance on inherency would be erroneous in the absence of evidence or a clear and convincing explanation. *Ex parte Levy*, 17 U.S.P.Q2d 1461, 1464 (B.P.A.I. 1990). In this regard, a holding of inherency must flow as a necessary conclusion from the prior art, not simply a possible one:

The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art); *In re Oelrich*, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981). "To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (citations omitted)..."

MPEP 2112 IV.

Reconsideration and withdrawal of the claim rejection under 35 U.S.C. § 102 in view of DiCosmo are therefore requested.

#### **Rejection under 35 U.S.C. 102(b) over Whitbourne**

Claims 1, 3-7, 30 and 35 have been rejected under 35 U.S.C. 102(b) as being anticipated by Whitbourne. This rejection and its supporting remarks are respectfully traversed.

Whitbourne discloses "lubricious" coatings. Here again, magnetic resonance imaging is not disclosed, much less so the concept of the present claims. Moreover, there is no support for a holding of inherency. See the prior decisions cited above as authority.

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Reconsideration and withdrawal of the claim rejection under 35 U.S.C. § 102 in view of Whitbourne are therefore requested.

**Rejection under 35 U.S.C. 102(b) over Weissleder**

Claims 1, 3-5, 10, 11, 15-22, 28-31 and 35 have been rejected under 35 U.S.C. 102(b) as being anticipated by Weissleder. This rejection and its supporting remarks are respectfully traversed.

For imaging visibility, Weissleder discloses loading the hydrogel with diagnostic labels, such as a gadolinium containing compound. See Weissleder Abstract and col. 4, lines 1-8. Weissleder discloses cross-linking, but only to ensure insolubility of the hydrogel disclosed. See, e.g., col. 6, lines 33-39. The concept of controlling or modifying the degree of visibility to MRI by varying the degree of cross-linking is not disclosed. See *Ex parte Rubin, supra*. The importance of this limitation is illustrated in paragraphs [0033] and [0039] and in Example 6 of the instant specification.

Because each and every element of the here-claimed invention is not disclosed in Weissleder reference, the reference clearly fails as an anticipation. See MPEP 2131 and the precedents cited above.

It is possible that the Examiner may be focusing on col. 6, lines 33-39 of Weissleder in which it is stated that "[t]hese hydrogels include a polymeric backbone insolubilized by cross-linking agents which allow the hydrogels to absorb large amounts of water, which makes them well suited for proton relaxation imaging, e.g., MRI." In this regard, it well known that paramagnetic materials, e.g., paramagnetic ions such as gadolinium ions, require the proximity of water or another proton-bearing substance, in order to provide enhanced contrast under MRI. See, e.g., the background section of the present specification, including, paragraph [0009].

This concept is, of course, remote from the present invention, in which the degree of visibility to MRI is controlled by varying the degree of cross-linking. For instance, see, e.g., paragraph [0033] and Example 6 (note that Glascol WN33 is a copolymer of sodium acrylate and acrylamide) of the instant specification. The use of paramagnetic materials in the dependent claims is to further enhance the degree of visibility provided by the cross-linking recited in the independent claim.

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Moreover, there is no support for a holding of inherency. See the prior decisions cited above as authority.

For the above reasons, reconsideration and withdrawal of the claim rejection under 35 U.S.C. § 102 in view of Weissleder are requested.

**Rejection under 35 U.S.C. § 103 over Weissleder and Michaels**

Claims 6-8 have been rejected under 35 U.S.C. 103(b) as being unpatentable over Weissleder in view of Michaels. This rejection and its supporting remarks are respectfully traversed.

Claim 6-8 ultimately depend on claim 1 and, thus, includes all of the limitations of claim 1. Thus, the hydrogel polymer must be cross-linked to a degree sufficient to render the medical device visible under magnetic resonance imaging.

The defects in Weissleder as a reference have been discussed above. Glycerin is taught by Michaels only as a plasticizer, not as a proton source for MRI imaging. The combination of Michaels with Weissleder can in no way remedy those defects.

Moreover, there is no teaching, suggestion, or motivation to combine or modify the teachings of the Weissleder and Michaels, either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art. In the absence of any such teaching, suggestion or motivation, the combination of reference teachings can only be made with the use of undue hindsight. See MPEP 2142, second paragraph.

Furthermore, even assuming for the sake of argument that the references may be combined or modified as argued by the examiner, there is no support for a holding of inherency. See the prior decisions cited above.

Reconsideration and withdrawal of the claim rejection under 35 U.S.C. § 103 over Weissleder in view of Michaels are therefore requested.

**Rejection under 35 U.S.C. 103 over Weissleder and Klaveness**

Claim 12 has been rejected under 35 U.S.C. 103(a) as being unpatentable over Weissleder in view of Klaveness. This rejection and its supporting remarks are respectfully traversed.

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Claim 12 is ultimately dependent on claim 1 and, thus, includes all of the limitations of claim 1, as well as intervening claims in the chain of dependency. Thus, the property of MRI visibility is first provided by cross-linking, and the use of other known opacifiers is an optional embodiment.

Consequently, to whatever extent these references may or may not be properly combinable, their combination would not result in the invention of claim 12.

Reconsideration and withdrawal of the claim rejection under 35 U.S.C. § 103 over Weissleder in view of Klaveness are therefore requested.

**Rejection under 35 USC § 103 over Weissleder and Peng**

Claim 23 has been rejected under 35 U. S. C. 103(a) as being unpatentable over Weissleder in view of Peng. This rejection and its supporting remarks are respectfully traversed.

This rejection is inadequate because of the defects in Weissleder as a reference (described above) and because Peng does not remedy those defects.

As pointed out in applicants' previous response, Peng deals with pharmaceutical compositions and not with medical devices or MRI. With no motivation or suggestion in the references, to take a chelating compound from Peng and incorporate it into Weissleder involves the use of undue hindsight guided only by the instant disclosure. See MPEP 2142, second paragraph, discussed above.

Moreover, even assuming for the sake of argument that the references may be combined or modified as argued by the examiner, there is no support for a holding of inherency. See the prior decisions cited above as authority.

Reconsideration and withdrawal of the claim rejection under 35 U.S.C. § 103 over Weissleder in view of Peng are therefore requested.

**Rejection under 35 USC § 103 over Weissleder and Cleary**

Claims 24-27, 32 and 33 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Weissleder in view of Cleary. This rejection and its supporting remarks are respectfully traversed.

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Weissleder is deficient as a reference for the reasons discussed above, and Cleary does not make up for those deficiencies.

Moreover, Cleary is relied on for the specific polymers of acrylic acid and acrylamide. Those polymers are used in a completely different environment from Weissleder and the instant claims. It should be noted that all of the polymers disclosed as useful by Weissleder appear to be naturally occurring or slightly modified naturally occurring polymers. There is no disclosure of anything like polymers or copolymers of acrylic acid and acrylamide. Thus, the disclosure of Weissleder actually teaches away from the use of those polymers and copolymers. *In re Baird*, 29 U.S.P.Q.2d 1550, 1552 (Fed. Cir. 1994).

In addition, even assuming for the sake of argument that the references may be combined or modified as argued by the examiner, there is no support for a holding of inherency. See the prior decisions cited above.

Furthermore, one of ordinary skill in the relevant art would not have had a reasonable expectation of success for the substitution of polymers suggested by the examiner. See MPEP 2143.02 and the cases cited therein. See in particular *In re Rinehart*, 531 F.2d 1048, 189 U.S.P.Q. 143, 148 (CCPA 1976), in which it was held that inherency and obviousness are two entirely different concepts, and allegations of inherency do not substitute for a showing of reasonable expectation of success.

To a large extent this rejection, and the other rejections under 35 U.S.C. 103 discussed herein, reflect the long discredited "obvious-to-try" standard. See, merely for a recent example, *Ex parte Erlich*, 3 U.S.P.Q.2d 1011 (B.P.A.I. 1986).

Reconsideration and withdrawal of the claim rejection under 35 U.S.C. § 103 over Weissleder in view of Cleary are therefore requested.

**Rejection under 35 USC § 103—Weissleder**

Claims 34, and 36-38 have been rejected under 36 U.S.C. 103(a) as being unpatentable over Weissleder. This rejection and its supporting remarks are respectfully traversed.

This rejection, as did the rejection for anticipation, relies on an assertion of inherency supported only by unfounded speculation. That issue has been discussed at

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length above. In this rejection the examiner has relied also on statements of obviousness with no supporting authority. Applicant challenges what is in effect taking official notice of the relevant facts. See MPEP 2144.03.

Reconsideration and withdrawal of the claim rejection under 35 U.S.C. § 103 over Weissleder are therefore requested.

**Examiner's response to arguments**

In the final rejection, the examiner did not address the issues of suggestion and motivation to combine the references, the use of undue hindsight, and reasonable expectation of success. Instead, the examiner has erroneously characterized the critical limitations of the claims as being "directed to the intended use of the device" and process limitations that do not "add any further structural limitations."

In the discussion of the first rejection under 35 U.S.C. 102, Applicant explained the partial product-by-process nature of the instant claims. Each process limitation recited results in a specific property of the claimed structure, not an intended use. The intended use is reflected in the withdrawn process claims. MRI visibility and having the ability to vary that visibility are properties. Varying the degree of cross-linking is a process step that results variation in MRI visibility, a property. In other words, the controverted limitations actually describe properties of the claimed structure, not merely a function. But even if they did, the claims would still distinguish over the prior art. *In re Swinehart*, 439 F.2d 210, 169 U.S.P.Q. 226, 228 (CCPA 1971). See also, *In re Fuetterer*, 319 F.2d 259, 138 U.S.P.Q. 217, 222 (CCPA 1963).

Product-by-process and product-by-property are both acceptable forms of claiming an article or compound. See, merely for example, *E. I. DuPont de Nemours & Co. v. Phillips Petroleum Co.* 849 F.2d 1430, 7 U.S.P.Q.2d 1129 (Fed. Cir. 1988). See also, *In re Metcalfe*, 410 F.2d 1378, 161 U.S.P.Q. 523, 793 (CCPA 1969).

The new matter rejection has been fully treated above.



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**CONCLUSION**

In light of the foregoing amendments and remarks, it is believed that all of the rejections of record have been obviated. Allowance of this application is therefore respectfully requested.

**FEES**

While it is not believed that any fees are due as a result of this Amendment, the Examiner is authorized to charge any fees that may be due to the undersigned attorney's PTO Deposit Account #50-1047.

Respectfully submitted,

By:



Attorney for Applicant  
Mayer & Williams, PC  
251 North Avenue West, 2<sup>nd</sup> Floor  
Westfield, NJ 07090

David B. Bonham  
Reg. No. 34,297

Tel.: 703-433-0510  
Fax: 703-433-2362

**CERTIFICATE OF FACSIMILE TRANSMISSION**

I hereby certify that this document, and any document referenced herein, has been transmitted via facsimile to the US Patent and Trademark Office at 571-273-8300 on Sept. 14, 2005.

**David B. Bonham, Reg. No. 34,297**  
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